VACCINATE YOUR FAMILY

The Journey of Bringing a Vaccine to Market

Vaccines are essential in preventing infectious diseases, but developing and bringing one to market is a complex and highly regulated process. Here's a concise overview of the journey a vaccine takes before reaching the public:

1. Research and Development (Preclinical Stage)

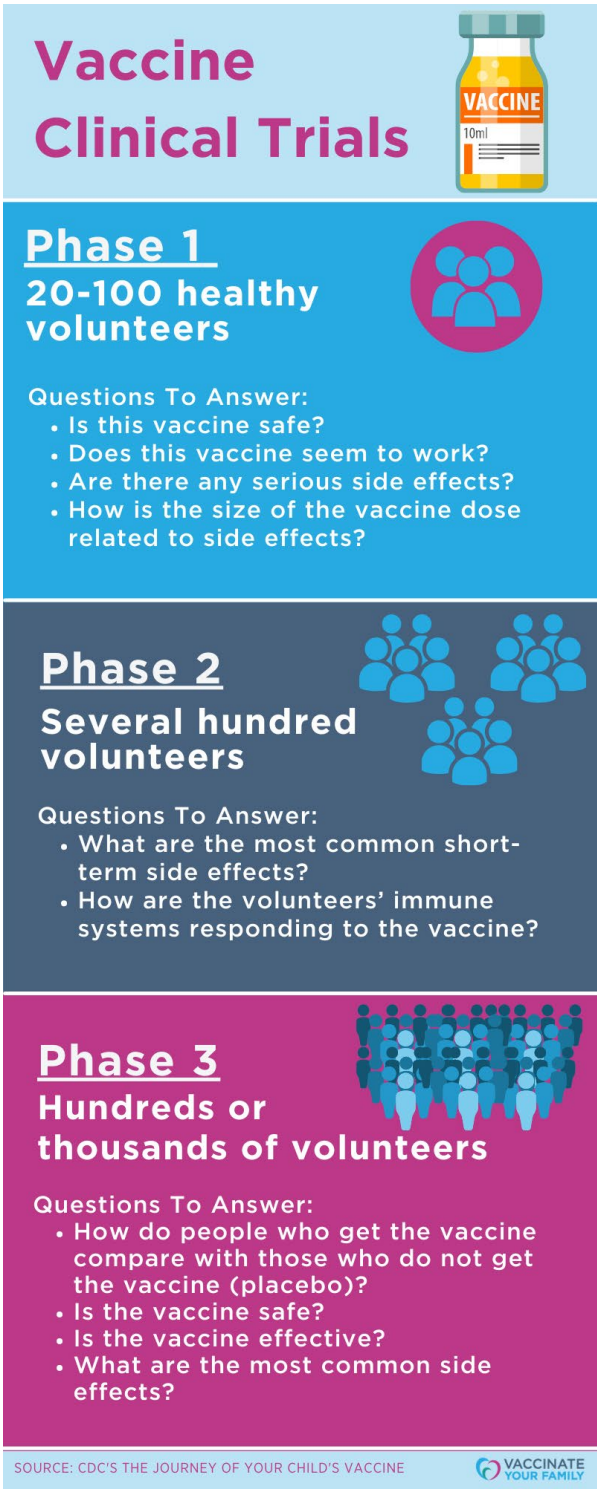
- **Exploratory Research**: Scientists study diseases, identify potential targets, and design vaccine candidates. This phase includes laboratory work and early testing.
- **Preclinical Studies**: Vaccine candidates are tested on cells and animals to evaluate safety and immune response. Only the most promising candidates move forward.

2. Clinical Trials (Human Testing) Vaccines must undergo **rigorous testing in three phases** to ensure safety and effectiveness:

- **Phase 1**: A small group of healthy volunteers (20-100 people) receives the vaccine to assess safety and determine the correct dosage.
- **Phase 2**: Hundreds of participants receive the vaccine, including those from target demographic groups, to study its efficacy and side effects.
- **Phase 3**: Thousands to tens of thousands of participants are involved to confirm safety, effectiveness, and identify rare side effects. This phase often spans multiple countries to ensure diverse population testing.

3. Regulatory Review and Approval

- **FDA Submission**: Vaccine manufacturers submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA), providing all data from preclinical and clinical trials.
- **FDA Review**: Experts thoroughly review the data to ensure the vaccine meets stringent safety and efficacy standards. An advisory committee may be convened for additional evaluation. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) consists of experts knowledgeable in the fields of immunology, vaccine safety science, vaccine development, infectious diseases, and more. Several steps are taken prior to committee meetings to ensure no conflicts of interest exist, particularly for voting members. The FDA also assesses information regarding the manufacturing of the vaccine and the facility to ensure the vaccine can be produced reliably and consistently.
- **Approval**: If the FDA is satisfied, the vaccine receives approval for public use.



4. Manufacturing and Quality Control

- **Scale-Up Production**: Vaccine production is scaled up to meet population needs, using tightly controlled processes to ensure consistency.
- **Quality Assurance**: Manufacturers conduct ongoing tests for safety, potency, and purity. Regulatory agencies inspect facilities regularly.

5. Distribution and Monitoring

- **Distribution**: Vaccines are shipped to healthcare providers, clinics, and pharmacies under strict conditions to maintain their effectiveness.
- **Post-Market Surveillance**: Vaccines undergo continuous monitoring to identify any long-term side effects or rare adverse events. There are several systems in place to detect vaccine safety issues:
    - **Vaccine Safety Datalink (VSD)** – VSD is a collaborative project between CDC's Immunization Safety Office and healthcare networks and organizations across the United States. This system uses databases of medical records to track the safety of vaccines. Since it uses medical records instead of self-reports like VAERS uses, this system can better help determine if a side effect is linked to a vaccine, especially rare and serious adverse events following vaccination.
    - **Clinical Immunization Safety Assessment (CISA) Project** – CISA is a national network of vaccine safety experts from the CDC's Immunization Safety Office and several medical research centers and partners. This project addresses safety issues, conducts high quality clinical research, and assesses complex clinical adverse events following vaccination. CISA also helps to connect clinicians with experts who can help consult on vaccine safety questions related to individual patients.
    - **Vaccine Adverse Events Reporting System (VAERS)** – VAERS is a passive, early warning system that is managed by CDC and FDA and designed to alert both entities to safety issues. Anyone can report an injury, including healthcare professionals, patients, patient representatives, vaccine companies, and others. Since anyone can report their own vaccine issue, VAERS reports cannot be used to determine a link between a side effect and vaccine, however, the information can be used to see if unexpected or unusual patterns emerge that may indicate a safety issue that should be explored further.

Key Considerations for Vaccine Development

- **Timeframe**: Developing a vaccine typically takes 10-15 years, but advancements in technology (e.g., mRNA vaccines) have shortened timelines in some cases.
- **Ethics and Equity**: Ensuring equitable access to vaccines is a critical challenge, particularly in low-resource settings.

Reliable Resources for More Information

- Centers for Disease Control and Prevention (CDC): cdc.gov/vaccines
- World Health Organization (WHO): who.int/news-room/feature-stories/detail/how-are-vaccines-developed
- U.S. Food and Drug Administration (FDA): fda.gov/vaccines-blood-biologics

For more information, visit **Vaccinate Your Family** at vaccinateyourfamily.org.